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10/606,304

06/25/2003

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

02/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/606,304

Applicant(s)

DANIELS ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/22/2006, 11/02/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 70-76 and 78-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-69 and 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 01/09/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2006 has been entered.

### ***Specification***

The abstract of the disclosure is objected to because it contains phrases that can be implied and should be avoided, e.g. "In an embodiment of the present invention." Also, the abstract is not a concise statement of the technical disclosure of the patent application and does not include that which is new in the art to which the invention pertains. Furthermore, the abstract should not include the purported merits of the speculative application of the invention, i.e. "alleviates discomfort and lack of stability..." and "alleviates pain and increases lumbosacral stability...". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an

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improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### ***Claim Objections***

Claims 1-6 are objected to because of the following informalities: In claim 1, lines 5, "the lateral plane" should be changed to --a lateral plane-- to be clearer for examination purposes. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Shirado et al. (U.S. Patent Application Publication No. 2003/0109882).

Shirado et al. disclose a spacer (ref. #33, FIG. 6) with a first end cylindrically shaped (ref. #33F) about an axis, wherein the first end is not attached to the spinous process of the first vertebra, and a beam (ref. #33B) extending from the first end, and a base adapted to be mounted, or capable of being mounted, to a second vertebra with the beam mounted to the base (ref. #35, 15), wherein the beam extends beyond the mounted base, where the base is adapted to be hung on the second vertebra, where the base is secured by an action of the first end contacting the first vertebra. An aperture (ref. #35H) accepts a post (ref. #37S) in a plurality of positions. The cross section of the spacer is oval/circular (see FIG. 2A). The implant is capable of being positioned between the S1 and L5 vertebrae.

Claims 7-9, 13-26, 30-43, 47-58, 61-69 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose an implant comprising a body/base (FIG. 1, ref. #22), at least one hook/flange extending from the body capable of allowing the body to engage a vertebra (FIG. 1, ref. #30 and #50), a beam extending from the body (FIG. 8, ref. #90), the beam having a distal end that can contact a spinous process of another vertebra, and a device that secures the beam to the body (FIG. 8, ref. #80) and contacts the beam directly (col. 5, lines 35-36) [claim 26]. The beam extends beyond the body and extends beyond the hook (in the vertical direction). The device secures the beam to the body in a plurality of positions (col. 5, lines 31-46). The distal end of the beam, the spacer, is bulbous and is round (FIG. 8, ref. #90). The beam includes an elongated aperture (FIG. 8, ref. #92). The elongated aperture of the beam receives a post extending from the base (FIG. 8, ref. #80). A lock cooperates with the post of the base to secure the beam to the base (FIG. 1, ref. #82). The device extends through the aperture and can be secured to the aperture in a plurality of positions in order to position the beam relative to the body in a plurality of positions (col. 5, lines 31-46). The body includes a first portion and a second portion (FIG. 2, ref. #32 and #52) with a beam platform located between the first and second portions (FIG. 1, ref. #70). There is a space between the platform and first and second portions. The hook extends from the first portion and another hook extends from the second portion. The device extends from the platform. The implant comprises a device that is capable of securing the base to an S1 vertebra (FIG. 2, ref. #72). The spacer (FIG. 8, top end part of ref. #90) has a

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first end capable of contacting the spinous process of a first vertebra without being attached to the spinous process of the first vertebra, and a beam extending from the first end (FIG. 8, ref. #90). The spacer (ref. #90) has a curved surface about its central longitudinal axis. The central longitudinal axis is parallel to the plane of the beam and parallel to a plane of the proximal end. The beam is capable of being mounted to the base, or body, (ref. #22) and the base is capable of being mounted to a second vertebra. The distal end of the beam provides a surface that is at an angle to the beam. The surface is capable of engaging L5 vertebra. The surface that is capable of spreading a contact load between a L5 vertebra and the distal end. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra without being attached to a second vertebra. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra over a conforming contact area. The implant is capable of being positioned between the S1 and L5 vertebra, without being attached to the L5 vertebra. The distal end of the beam includes a convex surface (FIG. 8, ref. #90) that is capable of engaging a spinous process of a L5 vertebra in order to spread the load between the distal end of the beam and the spinous process of the L5 vertebra. No additional hooks extend, or stretch out to a greater length, in a direction opposite the first direction, since hook 24 is stationary and does not extend, while hooks ref. #30 and ref. #50 are the only hooks that can extend [claim 43].

With regard to claims 7 and 8, these claims are being rejected under a second interpretation of the reference. A spacer (ref. #70) is adapted to contact a spinous process wherein the spacer is not attached to the spinous process, a base (ref. #22)

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having at least a flange (ref. #30) adapted to engage a second vertebra, the spacer engaging the base, wherein the spacer extends beyond the base and the flange, and the spacer is in direct contact with the base [claim 7]. The spacer (ref. #70) has a curved surface at the first end (top portion of ref. #70). The surface is curved about the longitudinal axis of the spacer, and the longitudinal axis is parallel to the planar surface at the second end (the flat surface at the bottom portion of ref. #70).

With regard to the statements of intended use and other functional statements, e.g. the functional limitations added to claims 1 and 9, they do not impose any structural limitations on the claims distinguishable over Lee et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious



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at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 27-29, 44-46, and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Lee et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments filed 11/02/2006 have been fully considered but they are not persuasive. See underlined portions in the above rejections for segments of the rejections most pertinent to the following comments.

The Abstract is still objected to (see above), and the examiner has provided underlined portions for emphasis.

Applicant asserts that the Lee et al. Reference does not disclose a spacer with "a distal end with a curved surface formed about an axis and a proximal end that is planar, wherein the axis is parallel to the plane of the proximal end." The examiner respectfully disagrees that the Lee et al. reference does not disclose those limitations. Below the examiner is providing marked-up figures to illustrate that the Lee et al. reference does indeed meet those limitations.



the above figure. Similar is true for the second interpretation for claims 7 and 8, which refers to ref. #70 as the spacer rather than ref. #90.

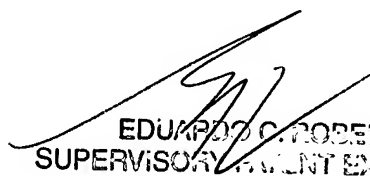
Therefore, the rejections are deemed proper.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER